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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS : HUBERT DORN ET AL.
SERIAL NO. : THIRD DIVISION OF U.S. SERIAL NO. 08/925,372 FILED ON
SEPTEMBER 8, 1997
FILED : HEREWITH
FOR : NON-SYSTEMIC CONTROL OF PARASITES
ART UNIT : 1617
EXAMINER : A. Robinson

February 9, 2001

Hon. Commissioner of Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

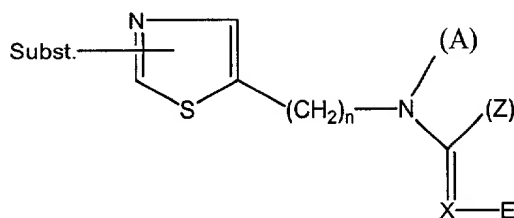
SIR:

Prior to examination, please amend the above-identified application as follows:

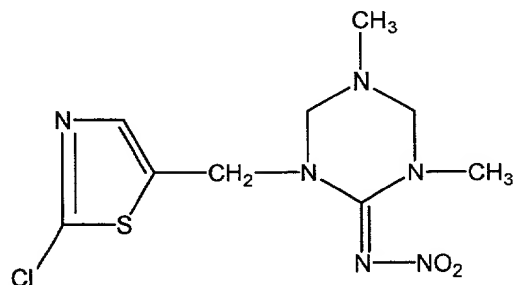
IN THE SPECIFICATION:

Please insert as the first sentence: -- This application is a division of U.S. Serial No. 08/925,372, filed on September 8, 1997, now pending; which is a continuation of U.S. Serial No. 08/440,428, filed May 12, 1995, now abandoned.--

Page 6, second formula after line 5, delete and substitute:



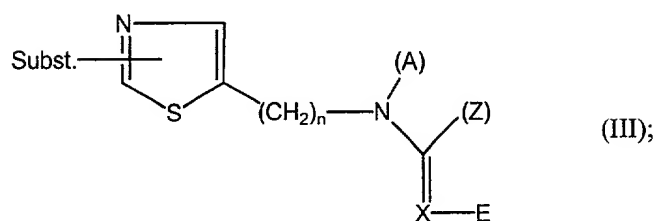
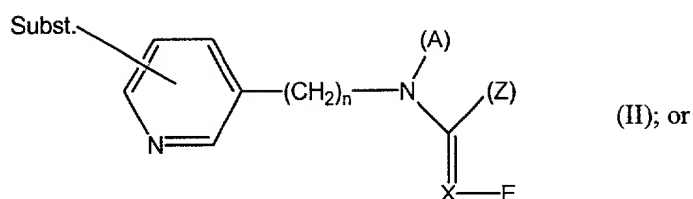
Page 7, first row of formulas, second formula in that row, delete and substitute:



IN THE CLAIMS:

Cancel all of the claims in the application and substitute:

--10. A method for non-systemically controlling a parasitic insect selected from fleas and lice on a human or animal, said method comprising contacting said parasitic insect with an effective amount therefor of a compound of the formula:



wherein

n represents 1 or 2;

Subst. represents halogen;

A and Z together with the nitrogen and carbon atom to which they are bonded form a saturated heterocyclic ring having 6 ring members, said heterocyclic ring containing in addition to the nitrogen atom to which A is bonded a further hetero group, said hetero group being selected from N-H and N-alkyl, wherein the alkyl of said N-alkyl has 1 to 4 carbon atoms;

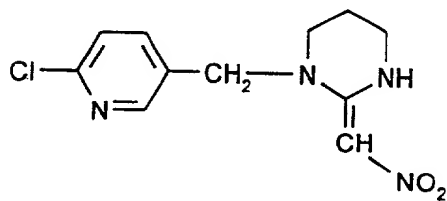
E represents NO_2 or CN ; and

X represents $-\text{CH}=\text{}$ or $-\text{N}=\text{}$;

wherein said contacting of said parasitic insect with said compound is effected by:

- a) topically applying said compound to the dermis of said human or animal; or
- b) contacting the dermis of said human or animal with an article containing said compound.--

--11. The method according to claim 10, which comprises contacting said parasitic insect with the compound:



--12. The method according to claim 10, wherein the animal is a dog or cat

infested with fleas.--

--13. The method according to claim 12, wherein said contacting is effected by applying said compound topically to the dermis of said dog or cat by a pour-on or spot-on method.--

--14. The method according to claim 12, wherein said contacting is effected by contacting the dermis of said dog or cat with an article containing said compound.--

--15. The method according to claim 10, which is carried out on a human, and the human is infected with lice.--

REMARKS

Applicants point out that two obvious errors have been corrected in the specification on pages 6 and 7, as indicated above. The formula (III) on page 6 was missing a bond in the thiazolyl ring. Likewise, the second formula in the first row of formulas on page 7 was also missing a bond in the thiazolyl ring. These errors are obvious and do not introduce new matter since R in formula (I) on page 2 permits only *heteroarylalkyl* as the relevant definition, and the original structures, which have now been corrected, are not *heteroarylalkyl*, whereas the corrected structures are. In short, considering the definition of R on page 2 of the specification, it

would have been obvious to any person skilled in the art that the formula (III) on page 6 and the second formula on page 7 were incorrect, and that these incorrect formulas should be corrected as now done. Accordingly, Applicants respectfully request that the Examiner accept these amendments, as done in the parent, since these amendments do not introduce new matter. An early notice that these amendments have been accepted is earnestly solicited.

Regarding the claims, these have the same form as those examined in the parent. The only difference is the particular compound which is being used in the claimed method. For the Examiner's convenience, Applicants point out that the form of the present claims corresponds to that of the parent claims as follows:

| <u>Instant Claim:</u> | <u>Corresponding Parent Claim:</u> |
|-----------------------|------------------------------------|
| 10 | 17 |
| 11 | 18 |
| 12 | 22 |
| 13 | 23 |
| 14 | 24 |
| 15 | 25 |

Regarding the subgenus of compounds claimed in new main claim 10, Applicants point out that the various limitations are supported by the instant specification as follows:

| LIMITATION | SUPPORT |
|---|--|
| Formulas (II) and (III); definition of n; and definition of Subst. | Page 6, lines 4-12 |
| A and Z together with the nitrogen and carbon atom to which they are bonded form a saturated heterocyclic ring having 6 ring members, said heterocyclic ring containing in addition to the nitrogen atom to which A is bonded a further hetero group, said hetero groups being selected from N-H and N-alkyl, wherein the alkyl of said N-alkyl has 1 to 4 carbon atoms | Page 6, line 12 ("A, Z * * * have the abovementioned meanings") read in conjunction with page 4, last line through page 5, line 7 ("A and Z together with the atoms to which they are bonded can form a saturated * * * heterocyclic ring. The heterocyclic ring can contain 1 * * * hetero atoms and/or hetero groups. Hetero atoms are preferably * * * nitrogen [N-H], and hetero groups are N-alkyl, the alkyl of the N-alkyl group preferably containing 1 to 4 * * * carbon atoms. * * * The heterocyclic ring contains * * * preferably * * * 6 ring members.") |
| E represents NO ₂ or CN | Page 6, line 12 ("* * * E have the abovementioned meanings") read in conjunction with page 5, lines 11-13 ("E represents * * * in particular, NO ₂ , CN") |
| X represents -CH= or -N= | Page 6, line 12 ("* * * X * * * have the abovementioned meanings") read in conjunction with page 5, line 14 ("X represents -CH= or -N=") |

In addition, Applicants point out that the compound of claim 11, which appears in the specification on pages 6-8, falls within, and, therefore, also supports the subgenus of new main claim 10.

In short, Applicants submit that new claim 10 finds ample support in the instant

specification, and that no new matter is contained in claim 10. An early notice to that effect is earnestly solicited.

During the prosecution of the parent application, the claims therein were rejected under 35 USC § 103(a) as being obvious over Kristiansen et al. ("Kristiansen"), U.S. Patent No. 5,302,605, Shiokawa et al. ("Shiokawa"), U.S. Patent No. 4,914,113, Elbert et al. ("Elbert"), *Brighton Crop Protection Conference*, pages 21-28 (1990), Derwent Abstract of JP 03,279,359 ("the Japanese patent") and EP 0 285 985, and Applicants presume that a similar rejection might have been made here. However, Applicants point out that the cited references do not teach or suggest *non-systemic control* of parasitic insects selected from fleas and lice in the manner required by the present claims. Moreover, the data submitted during the prosecution of the parent application established that the instantly claimed control method provided results that were unexpectedly superior to that provided by other control methods, namely, oral treatment. For the Examiner's convenience, there are attached copies of all of the declarations filed during the prosecution of the parent application.

The data that first led to an indication of allowable subject matter was the declaration of Dr. Olaf Hansen executed on February 15, 2000. As can be seen most clearly from the table on page 10 of the declaration, *dermal treatment* using every tested compound provided a superior flea treatment for a much longer time than did the corresponding *oral treatment*. Indeed,

whereas the efficacy of the *oral treatment* was good for a few days only, the efficacy of the *dermal treatment* was much longer, for a number of weeks, and in some cases, lasting for a month or more. There is absolutely nothing in the cited prior art that would have led a person skilled in the art to suspect that the results obtained with *dermal treatment* should be superior to those obtained with *oral treatment*. Accordingly, the data in the Hansen Declaration must be regarded as surprising and unexpected, and, therefore, as objective evidence of nonobviousness.

Further, the data in the Hansen Declaration and the other data of record shows that the advantages of the present invention are obtained irrespective of whether R = optionally substituted pyridylmethyl or thiazolylmethyl, or indeed whether A and Z are acyclic or together for a cyclic structure. Applicants submit that these facts provide reasonably assurance that the instantly claimed compounds all share the advance now urged over the prior art. Consequently, Applicants respectfully request that the Examiner accept these data as reasonably representative of the instant claims.

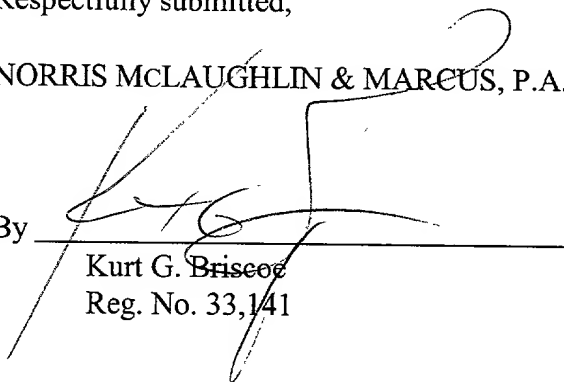
In view of the foregoing, Applicants submit that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (914) 332-1700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

NORRIS MCLAUGHLIN & MARCUS, P.A.

By

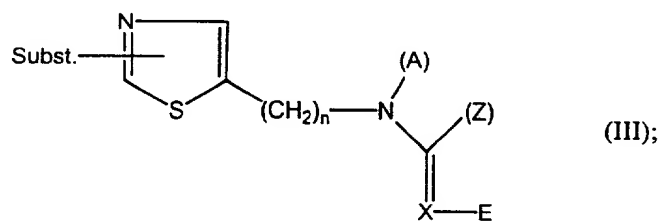
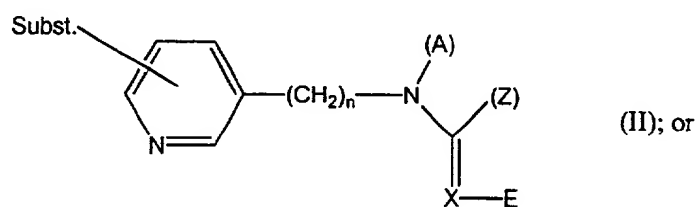


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CLEAN SET OF CLAIMS

--10. A method for non-systemically controlling a parasitic insect selected from fleas and lice on a human or animal, said method comprising contacting said parasitic insect with an effective amount therefor of a compound of the formula:



wherein

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A and Z together with the nitrogen and carbon atom to which they are bonded form a saturated heterocyclic ring having 6 ring members, said heterocyclic ring containing in addition to the nitrogen atom to which A is bonded a further hetero group, said hetero group being selected from N-H and N-alkyl, wherein the alkyl of said N-alkyl has 1 to 4 carbon atoms;

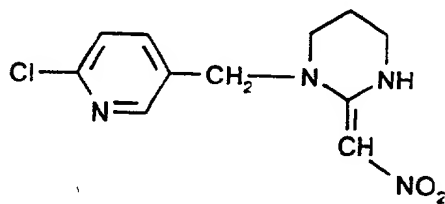
E represents NO₂ or CN; and

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